REMARKS

Claims 1-10, 12, 14, 17-31, 33, 36-48, 50, 52, 55-110 are pending in this application. Claims 1, 12, 14, 17-20, 33, 36-39, 50, 52, and 55-62 have been amended. Claims 11, 13, 15-16, 32, 34-35, 49, 51, and 53-54 are canceled. New Claims 63-110 have been added. Support for the amendments and new claims is found in the specification and claims as filed.

Claim Rejections - 35 U.S.C. § 103(a) – Mastrototaro in view of Shin et al.

Claims 1-10, 15-30, 34-48, and 50-62 have been rejected under 35 U.S.C. §103(a) as obvious over "The MiniMed Continuous Glucose Monitoring System," Diabetes Technology & Therapeutics, Volume 2, Supplement 1, 2000, Mary Ann Liebert, Inc., pp. S-13 to S-18 ("Mastrototaro") in view of U.S. Publ. No. 2002/0161288 (Shin et al."). To establish a *prima facie* case of obviousness, three basic criteria must be met: first, the prior art reference (or references when combined) must teach or suggest all the claim limitations; second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; finally, there must be a reasonable expectation of success. *See* M.P.E.P. § 2143. Mastrototaro and Shin et al., alone or in combination, do not teach or suggest all the claim limitations of the pending Claims 1-10, 15-30, 34-48, and 50-62, and therefore cannot render these claims obvious. Claims 15-16, 34-35, 51, and 53-54 have been canceled.

Claims 1-10, 15-30, 34-48, and 50-61

Pending Claim 1, from which pending Claims 2-10 and 17-19 depend, recites a method for evaluating a quality of a calibration of an analyte sensor comprising "receiving a data stream from an analyte sensor, including one or more sensor data points; receiving reference data from a reference analyte monitor, including one or more reference data points; providing at least one matched data pair by matching reference analyte data to substantially time corresponding sensor data; forming a calibration set including said at least one matched data pair; evaluating a quality of said calibration set using a data association function; converting sensor data into calibrated data using said calibration set; and *providing the calibrated data to a user interface only when the data association is above a predetermined threshold*" (emphasis added).

Pending Claim 20, from which pending Claims 21-30 and 36-38 depend, recites system for evaluating a quality of a calibration of an analyte sensor comprising "means for receiving a

data stream from an analyte sensor, a plurality of time-spaced sensor data points; means for receiving reference data from a reference analyte monitor, including one or more reference data points; means for providing one or more matched data pairs by matching reference analyte data to substantially time corresponding sensor data; means for forming a calibration set including at least one matched data pair; means for converting sensor data into calibrated data using said calibration set; and *means for providing calibrated data only when the data association is above a predetermined threshold*" (emphasis added).

Pending Claim 39, from which pending Claims 40-48, 50, 52, and 55-57 depend, recites system for evaluating a quality of a calibration of an analyte sensor comprising "means for receiving a data stream from an analyte sensor, a plurality of time-spaced sensor data points; means for receiving reference data from a reference analyte monitor, including one or more reference data points; means for providing one or more matched data pairs by matching reference analyte data to substantially time corresponding sensor data; means for forming a calibration set including at least one matched data pair; means for converting sensor data into calibrated data using said calibration set; and *means for providing calibrated data only when the data association is above a predetermined threshold*" (emphasis added).

Mastrototaro teaches that calibration and display both occur only when the quality of the calibration set, not a data association, is above a predetermined threshold. Likewise, Shin et al includes no teaching or suggestion of providing calibrated data to a user interface only when the data association is above a predetermined threshold. Accordingly, Applicants respectfully request that the rejection of Claims 1-10, 15-30, 34-48, and 50-57 be withdrawn.

Claims 58 and 60

Pending Claim 58 recites a method for evaluating a quality of a calibration of an analyte sensor comprising "receiving a data stream from an analyte sensor, including one or more sensor data points; receiving reference data from a reference analyte monitor, including one or more reference data points; providing at least one matched data pair by matching reference analyte data to substantially time corresponding sensor data; *forming a calibration set comprising no more than two matching data pairs for a single day*; and evaluating a quality of said calibration set based on an association of reference analyte data and substantially time corresponding sensor data for at least one matched data pair" (emphasis added).

Pending Claim 60 recites a computer system for evaluating a quality of a calibration of an analyte sensor comprising "a sensor data module configured to receive a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor; a reference input module configured to receive reference data from a reference analyte monitor, including one or more reference data points; *a processor module configured to form one or more matched data pairs by matching reference data to substantially time corresponding sensor data, wherein the processor module is further configured to form a calibration set including no more than two matched data pairs for a single day*; and a quality evaluation module configured to evaluate a quality of said calibration set based on an association of reference analyte data and substantially time corresponding sensor data for said at least one matched data pair" (emphasis added).

Mastrototaro does not teach or suggest a calibration set including no more than two matched data pairs for a single day. Instead, Mastrototaro explicitly teaches that teaches that the correlation coefficient cannot be meaningfully calculated when there are fewer than three meter-sensor data pairs for a single day (see page S-15). Likewise, Shin et al. includes no teaching or suggestion of a calibration set including no more than two matched data pairs for a single day. Accordingly, Applicants respectfully request that the rejection of Claims 58 and 60 be withdrawn.

Claims 59 and 61

Pending Claim 59 recites a method for evaluating a quality of a calibration of an analyte sensor comprising "receiving analyte sensor data from an analyte sensor; receiving reference data from a reference analyte monitor; providing at least one matched data pair by matching reference analyte data to substantially time corresponding sensor data; *evaluating a quality of said at least one matched data pair based on an association of reference analyte data and substantially time corresponding sensor data; and calibrating the sensor data comprising said at least one matched data pair responsive to the association above a predetermined threshold*" (emphasis added).

Pending Claim 61 recites a computer system for evaluating a quality of a calibration of an analyte sensor comprising "a sensor data module configured to receive analyte sensor data from a substantially continuous analyte sensor; a reference input module configured to receive reference

data from a reference analyte monitor; a processor module configured to form at least one matched data pair by matching reference data to substantially time corresponding sensor data; and *a quality evaluation module configured to evaluate a quality of said at least one matched data pair based on an association of reference data and substantially time corresponding sensor data for said at least one matched data pair, wherein the processor module is configured to calibrate the sensor data including said at least one matched data pair responsive to the association above a predetermined threshold*" (emphasis added).

Mastrototaro teaches retrospective calibration of all sensor data. Mastrototaro does not teach or suggest evaluating quality based on an association of reference data and substantially time corresponding sensor data, and calibrating the sensor responsive to the association above a predetermined threshold. Likewise, Shin et al. includes no teaching or suggestion of such an association and calibrating the sensor responsive to the association above a predetermined threshold. Accordingly, Applicants respectfully request that the rejection of Claims 59 and 61 be withdrawn.

Claim 62

Pending Claim 62 recites a method for evaluating a quality of a calibration of a glucose sensor comprising "receiving sensor data from a glucose sensor, including one or more sensor data points; receiving reference data from a reference glucose monitor, including one or more reference data points; providing one or more matched data pairs by matching reference glucose data to substantially time corresponding sensor glucose data; forming a calibration set including at least one matched data pair; *evaluating a quality of said calibration set based on a statistical analysis or a clinical acceptability analysis of at least one matched data pair; and processing real-time sensor data responsive to the quality of said calibration set above a predetermined threshold*" (emphasis added).

Neither Mastrototaro nor Shin et al. disclose processing real-time sensor data responsive to a quality of the calibration set above a predetermined threshold. Accordingly, Applicants respectfully request that the rejection of Claim 62 be withdrawn.

Claim Rejection - 35 U.S.C. §103(a) – Mastrototaro in view of Shin et al. and Sato et al.

Claims 12-14, 31-33, and 50-52 have been rejected under 35 U.S.C. §103(a) as obvious over Mastrototaro in view of Shin et al., in further view of U.S. Publication No. 2003/0023171 ("Sato et al.").

Claims 13, 32, and 51 have been canceled. Claims 12 and 14 depend from pending Claim 1. Claims 31 and 33 depend from pending Claim 20. Claims 50 and 52 depend from pending Claim 39. As discussed above in regard to pending Claims 1, 20, and 30, neither Mastrototaro nor Shin et al. teaches or suggests providing calibrated data to a user interface only when the data association is above a predetermined threshold. Sato et al. merely discloses use of a least squares regression to calculate a correlation coefficient. Sato et al. includes no teaching remedying the deficiencies of Mastrototaro and Shin et al. Accordingly, Applicants respectfully request that the rejection of Claims 12, 14, 31, 33, 50, and 52 be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 5/10/07

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AMEND

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